

PATENT/Docket No. 6231.N CN1

Serial No. 09/500246

Page 2

This listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims

Claims 1-25. (Canceled)

26. (Currently amended) An implant composition, suitable for implantation in an animal body by injection, comprising:

(a) a first component comprising a biologically active composition comprising melengestrol acetate, or a combination of melengestrol acetate and trenbolone acetate, or a combination of melengestrol acetate, and trenbolone acetate, and estradiol, contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in a animal body and which is selected from the group consisting of porous or freeze dried solid compositions, solid compressed tablets or and solid compressed pellets containing, comprising a disintegrating agent which causes the tablet or the pellet to rapidly break down when in body fluids, and wherein solid tablets or pellets containing said biologically active material composition is in fine or micronized particle sizes, or in freeze dried form, and or mixtures thereof; and

(b) a second component comprising the same biologically active composition as in component (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained release basis upon implantation in an animal body and which is selected from the group consisting of solid compressed tablets and solid compressed pellets, wherein said second delivery vehicle further comprises biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, conventional tablets or pellets containing said biologically active material having large particle sizes, matrix tablets based on gel-forming excipients, matrix type systems based on non-biodegradable polymers, membrane type systems based on non-biodegradable polymers, matrix type systems based on biodegradable polymers, matrix type systems implant based lipidic excipients, and mixtures thereof, and wherein said biologically active composition in the second delivery vehicle has large particle sizes.

27. (Currently amended) The implant composition of Claim 26 wherein the first delivery vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof containing a disintegrating agent and wherein the second vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof not containing a disintegrating agent.

28. (Previously presented) The implant composition of Claim 27, wherein said disintegrating agent is selected from the group consisting of sodium crosscarmellose, microcrystalline cellulose, sodium carboxymethyl-cellulose, alginic acid, starch, potassium polacrilin, colloidal silicon dioxide, crospovidone, guar gum, magnesium aluminum silicate, methyl cellulose, powdered cellulose, pregelatinized starch, sodium starch glycolate and sodium alginate and mixtures thereof.

29-31. (Canceled).

32. (Previously presented) The implant composition of Claim 26, wherein the melengestrol acetate is contained in each delivery vehicle in an amount of from about 5 to about 200 mg per delivery vehicle.

FORM PTORSP
Rev. 5/1/03

PATENT/Docket No. 6231.N CN1

Serial No. 09/500246

Page 3

33. (Previously presented) The implant composition of Claim 26 wherein either component (a) or component (b) or both further comprises one or more of the following materials: standard granulating aids, lubricants, diluents, binders and glidants, magnesium stearate, stearic acid, colloidal silicon dioxide, talc, titanium dioxide, magnesium, calcium and aluminum salts, lactose, cyclodextrins and derivatives thereof, starches, povidone, high molecular weight polyethylene glycols and derivatives thereof, bioerodible polymers and co-polymers, polystearates, carboxymethyl cellulose, cellulose, N,N-diethylamine acetate, polyvinyl alcohol, hydroxypropyl methyl cellulose, other biologically active or inactive substances or pharmaceutically active substances.

34. (Currently amended) An implant composition consisting essentially of:

(a) a first component comprising melengestrol acetate contained in one or more solid compressed pellets or solid compressed tablets or a mixture thereof capable of immediately releasing said melengestrol acetate upon implantation in an animal body, said pellet or tablet containing a disintegrating agent; and

(b) a second component comprising melengestrol acetate contained in one or more solid compressed pellets or solid compressed tablets or mixture thereof capable of releasing said biologically active composition-melengestrol acetate on a sustained basis upon implantation in an animal body, said pellet or tablet not containing a disintegrating agent;

wherein said implant composition is capable of being implanted in an animal body by injection.

35. (Previously presented) The implant of Claim 34, suitable for administration by a single injection, consisting essentially of one to four pellets of type (a) and four to six pellets of type (b).

36. (Currently amended) A method for delivering the same biologically active material to an animal body in both a rapid release and sustained release form comprising the steps of:

(1) providing an implant comprising:

(a) a first component comprising a biologically active composition comprising melengestrol acetate, a combination of melengestrol acetate and trenbolone acetate, or a combination of melengestrol acetate, trenbolone acetate and estradiol, contained in a first delivery vehicle capable of immediately releasing said biologically active composition upon implantation in an animal body and which is selected from the group consisting of porous or freeze dried solid compositions, solid compressed tablets, or solid compressed pellets, and mixture thereof, containing comprising a disintegrating agent which causes the solid tablet or pellet to rapidly break down when in body fluids, and wherein solid tablets or pellets containing said biologically active material composition is in fine or micronized particle sizes, or in freeze dried form, and or mixtures thereof; and

(b) a second component comprising the same biologically active composition as in component (a) contained in a second delivery vehicle capable of releasing said biologically active composition on a sustained basis upon implantation in an animal body and which is selected from the group consisting of solid compressed tablets and solid compressed pellets, wherein said second delivery vehicle further comprises biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, conventional tablets or pellets containing said biologically active

FORM PTORSP
Rev. 5/1/03

PATENT/Docket No. 6231.N CN1

Serial No. 09/500246

Page 4

~~material having large particle sizes, matrix tablets based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix-type systems based on biodegradable polymers, matrix-type systems implant based on lipidic excipients, and mixtures thereof; and wherein said biologically active composition in the second delivery vehicle has large particle sizes.~~

(2) injecting said implant into the animal body.

37. (Currently amended) The method of Claim 36 wherein the first delivery vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof containing a disintegrating agent and wherein the second vehicle comprises solid compressed tablets or solid compressed pellets or mixtures thereof not containing a disintegrating agent.

38. (Previously presented) The method of Claim 37, wherein said disintegrating agent is selected from the group consisting of sodium crosscarmellose, microcrystalline cellulose, sodium carboxymethyl-cellulose, alginic acid, starch, potassium polacrilin, colloidal silicon dioxide, crospovidone, guar gum, magnesium aluminum silicate, methyl cellulose, powdered cellulose, pregelatinized starch, sodium starch glycolate and sodium alginate and mixtures thereof.

39-41. (Canceled).

42. (Previously presented) The method of Claim 36, wherein the melengestrol acetate is contained in each delivery vehicle in an amount of from about 5 to about 200 mg per delivery vehicle.

43. (Previously presented) The method of Claim 36, wherein said animal is selected from the group consisting of cows, horses, sheep, swine, dogs, and cats.

44. (Previously presented) The method of Claim 43, wherein said animal is a heifer.

45. (Previously presented) The method of Claim 36 wherein said implanting step is selected from the group consisting of subcutaneous, intramuscular, intraperitoneal, and intracranial injections.

46. (Previously presented) The method of Claim 45 wherein said animal is a heifer and said implanting step comprises subcutaneous injection in the posterior of the ear of said heifer.

47. (Previously presented) The method of Claim 36 wherein step (2) comprises a single injection.

48. (New) The implant composition of Claim 26 wherein the preparation of said first delivery vehicle and said second delivery vehicle comprises the steps of 1) wet, dry, or fluid bed granulation or extrusion/spheronization; 2) particle screening and sizing; and 3) tablet or pellet compression.

49. (New) The method of claim 36 wherein the preparation of said first delivery vehicle and said second delivery vehicle comprises the steps of 1) wet, dry, or fluid bed granulation or extrusion/spheronization; 2) particle screening and sizing; and 3) tablet or pellet compression.

50. (New) The implant composition of Claim 26 wherein said second delivery vehicle is selected from the group consisting of matrix-type systems based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers, matrix

FORM PTORSP
Rev. 5/1/03

PATENT/Docket No. 6231.N CN1

Serial No. 09/500246

Page 5

type systems based on biodegradable polymers, matrix type systems based on lipidic excipients, and combinations thereof.

FORM PTORSP
Rev. 5/1/03